

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STEPHEN BUSHANSKY,

Plaintiff,

v.

AYALA PHARMACEUTICALS, INC., RONI
MAMLUK, MURRAY A. GOLDBERG,
ROBERT SPIEGEL, VERED BISKER-LEIB,
and DAVID SIDRANSKY,

Defendants.

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: Case No. _____
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: **COMPLAINT FOR VIOLATIONS OF**
: **THE FEDERAL SECURITIES LAWS**
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: JURY TRIAL DEMANDED
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Plaintiff Stephen Bushansky (“Plaintiff”), by and through his undersigned counsel, for his complaint against defendants, alleges upon personal knowledge with respect to himself, and upon information and belief based upon, *inter alia*, the investigation of counsel as to all other allegations herein, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This action is brought by Plaintiff against Ayala Pharmaceuticals, Inc. (“Ayala” or the “Company”) and the members of Ayala’s Board of Directors (the “Board” or the “Individual Defendants”) for their violations of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. §§ 78n(a), 78t(a), and U.S. Securities and Exchange Commission (“SEC”) Rule 14a-9, 17 C.F.R. § 240.14a-9, and to enjoin the vote on a proposed transaction, pursuant to which Ayala will merge with Advaxis, Inc. (“Advaxis”) through Advaxis’s subsidiary Doe Merger Sub, Inc. (“Merger Sub”) (the “Proposed Transaction”).

2. On October 19, 2022, Ayala and Advaxis issued a joint press release announcing entry into an Agreement and Plan of Merger, dated October 18, 2022, to merge Ayala with Advaxis (the “Merger Agreement”). Under the terms of the Merger Agreement, Ayala shareholders will receive 0.1874 shares of Advaxis common stock for each share of Ayala common stock they own (the “Merger Consideration”).

3. On December 15, 2022, Ayala caused to be filed a Definitive Proxy Statement on Schedule 14A (the “Proxy Statement”) with the SEC. The Proxy Statement, which recommends that Ayala stockholders vote in favor of the Proposed Transaction, omits, or misrepresents material information concerning, among other things: (i) Ayala management’s financial projections; (ii) and the data and inputs underlying the financial valuation analyses that support the fairness opinion provided by the Company’s financial advisor Torrey Capital, LLC (“Torrey”). The failure to disclose such material information constitutes a violation of Sections 14(a) and 20(a) of the Exchange Act as Ayala stockholders need such information to make a fully informed decision whether to vote in favor of the Proposed Transaction or seek appraisal.

4. In short, unless remedied, Ayala’s public stockholders will be forced to make a voting or appraisal decision on the Proposed Transaction without full disclosure of all material information concerning the Proposed Transaction being provided to them. Plaintiff seeks to enjoin the stockholder vote on the Proposed Transaction unless and until such Exchange Act violations are cured.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims asserted herein for violations of Sections 14(a) and 20(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder

pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1331 (federal question jurisdiction).

6. This Court has jurisdiction over the defendants because each defendant is either a corporation that conducts business in and maintains operations within this District or is an individual with sufficient minimum contacts with this District to make the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because defendants are found or are inhabitants or transact business in this District. Moreover, Ayala's common stock trades on the Nasdaq Global Market, which is headquartered in this District, rendering venue in this District appropriate.

THE PARTIES

8. Plaintiff is, and has been at all times relevant hereto, a continuous stockholder of Ayala.

9. Defendant Ayala is a Delaware corporation, with its principal executive offices located at Oppenheimer 4, Rehovot 7670104, Israel. Ayala is a clinical-stage oncology company. The Company's shares trade on the Nasdaq Global Market under the ticker symbol "AYLA."

10. Defendant Roni Mamluk ("Mamluk") has been President, Chief Executive Officer ("CEO"), and a director of the Company since November 2017.

11. Defendant Murray A. Goldberg ("Goldberg") has been a director of the Company since December 2017.

12. Defendant Robert Spiegel ("Spiegel") has been a director of the Company since December 2017.

13. Defendant Vered Bisker-Leib (“Bisker-Leib”) has been a director of the Company since August 2020.

14. Defendant David Sidransky (“Sidransky”) has been Chairman of the Board and a director of the Company since November 2017.

15. Defendants identified in paragraphs 10-14 are referred to herein as the “Board” or the “Individual Defendants.”

OTHER RELEVANT ENTITIES

16. Advaxis is a clinical-stage biotechnology company focused on the development and commercialization of proprietary antigen delivery products (“Lm Technology™”) based on a platform technology that utilizes live attenuated *Listeria monocytogenes* (“Lm”) bioengineered to secrete antigen/adjuvant fusion proteins. These Lm-based strains are believed to be a significant advancement in immunotherapy as they integrate multiple functions into a single immunotherapy by accessing and directing antigen presenting cells to stimulate anti-tumor T cell immunity, stimulate and activate the innate immune system with the equivalent of multiple adjuvants, and simultaneously reduce tumor protection in the Tumor Microenvironment (“TME”) to enable the T cells to attack tumor cells.

17. Merger Sub is a Delaware corporation and a direct, wholly-owned subsidiary of Advaxis.

SUBSTANTIVE ALLEGATIONS

Background of the Company

18. Ayala is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers. Ayala’s approach is focused on predicated, identifying, and addressing

tumorigenic drivers of cancer to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors including adenoid cystic carcinoma (“ACC”) and desmoid tumors. AL102 has received a designation from the U.S. Food and Drug Administration (the “FDA”) to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need (the “Fast Track” designation) and is currently in the Phase 2 portion of a pivotal study for patients with desmoid tumors (RINGSIDE). AL101 has received Fast Track designation and Orphan Drug Designation (“ODD”) a designation from the FDA under the Orphan Drug Act (“ODA”) intended to treat a rare disease or condition and is currently in a Phase 2 clinical trial for patients with ACC (“ACCURACY”) bearing Notch activating mutations.

19. On August 15, 2022, the Company announced its second quarter 2022 financial results and business developments. In July, Ayala announced positive interim data from Part A of the Phase 2/3 RINGSIDE study of AL102 in desmoid tumors: Data showed tumor shrinkage in substantially all patients who were evaluable at 16 weeks. AL102 was well tolerated at all three dosing regimens with no dose-limiting toxicities and no Grade 4/5 adverse events. The Company also presented data on AL101 in ACC presented at the ASCO 2022 Annual Meeting. In a poster at ASCO, the company provided an update from the 4mg and 6 mg AL101 cohorts in the ACCURACY study of AL101, a selective gamma-secretase inhibitor, in subjects with recurrent/metastatic (“R/M”) ACC harboring Notch activating mutations. An overall disease control rate of 66.7% was observed. Net loss was \$8.2 million for the second quarter of 2022, resulting in basic and diluted net loss per share of \$0.54. This compares with a net loss of \$10.8

million for the second quarter of 2021 or basic and diluted net loss per share of \$0.75 for that quarter. Reflecting on the Company's results, defendant Mamluk commented:

We continue to make considerable progress across our pipeline, and we were particularly excited to announce interim results from the ongoing Phase 2/3 RINGSIDE trial evaluating AL102 in desmoid tumors. Although early, the results showed substantial initial anti-tumor activity and a favorable side effect profile. Based on these positive results, our efforts are focused on finalizing the Part A of the study shortly followed by immediate initiation of Part B. For AL101, we were pleased with the latest interim results from the ACCURACY trial presented at ASCO, which demonstrated anti-tumor monotherapy activity and evidence of improved progression-free survival (PFS) in patients with recurrent/metastatic ACC.

The Proposed Transaction

20. On October 19, 2022, Ayala and Advaxis issued a joint press release announcing the Proposed Transaction, which states, in relevant part:

REHOVOT, Israel and WILMINGTON, Del. and MONMOUTH JUNCTION, N.J., Oct. 19, 2022 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA) (Ayala), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare tumors and aggressive cancers and Advaxis, Inc. (OTCQX: ADXS) (Advaxis), a biotechnology company devoted to the discovery, development and commercialization of immunotherapies based on a technology which uses engineered *Listeria monocytogenes*, today announced that they have entered into a definitive merger agreement. The merger would result in a combined company that will focus predominantly on the development and commercialization of Ayala's lead program AL102 for the treatment of desmoid tumors and Advaxis's candidate ADXS-504 in development for prostate cancer.

Kenneth A. Berlin, President and Chief Executive Officer of Advaxis, said, "Advaxis took a thorough approach in our quest to find the right partner with the right products. This merger is expected to enhance Advaxis's portfolio of clinical assets, with Ayala's proprietary gamma secretase inhibitors that are being developed as targeted therapies for rare and aggressive tumors. Ayala's lead candidate, AL102, is currently being investigated in the Phase 2/3 RINGSIDE study in desmoid tumors, which we believe will accelerate the stage of product development for the combined company dramatically. We are particularly excited about very promising interim data from RINGSIDE, which showed that AL102 monotherapy had meaningful anti-tumor activity with tumor shrinkage in the majority of patients that appeared to be deepening over time. The combined management team has extensive commercial and R&D experience, and we

believe we have the cash to advance the combined portfolio through key milestones in 2023, including longer-term data from Part A of RINGSIDE, clarity on the Proxypath for AL101 in recurrent/metastatic adenoid cystic carcinoma (ACC) and initial clinical and PSA data from the Phase 1 trial of ADXS-504 in prostate cancer. We believe that this transaction will also help drive our efforts to return to a Nasdaq listing and enhance our ability to access capital.”

Roni Mamluk, Ph.D., President and Chief Executive Officer of Ayala commented, “We are pleased to announce the proposed merger with Advaxis, which is expected to provide our pipeline and AL102 with additional financial resources as well as additional infrastructure in the U.S. The two companies have a shared mission to develop innovative therapies to improve the lives of patients with cancer and I believe we have found a good partner to advance our pipeline and create value for our stakeholders.”

Additional Transaction Details

Subject to the terms and conditions of the merger agreement, at the closing of the merger, each outstanding share of Ayala common stock will be converted into the right to receive shares of common stock of Advaxis based on the exchange ratio set forth in the merger agreement. Upon completion of the merger, Ayala stockholders will own approximately 62.5% of the combined company’s outstanding common stock and Advaxis stockholders will own approximately 37.5%, subject to the terms of the merger agreement. Advaxis will, at the effective time of the merger, assume the outstanding restricted stock units and stock options of Ayala, subject to the terms of the merger agreement. No fractional shares will be issued in connection with the merger and Advaxis will pay cash in lieu of any such fractional shares. The merger is intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Consummation of the merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Ayala. At the closing of the merger, Ayala will be delisted from The Nasdaq Global Market. The combined company’s common stock is expected to begin trading on the OTCQX at the effective time of the merger, subject to Advaxis’ planned efforts to have the stock of the combined company listed on Nasdaq, as to which no assurances can be made.

Management and Board of Directors

At the effective time of the merger, the executive officers of the combined company will include Mr. Kenneth A. Berlin, President, Chief Executive Officer and Director; Andres Gutierrez, M.D., Ph.D., current Chief Medical Officer of Advaxis; and Igor Gitelman, Interim Chief Financial Officer of Advaxis. Roni Mamluk, Ph.D., Founder and Chief Executive Officer of Ayala, and Yossi

Maimon, Chief Financial Officer of Ayala will resign their positions and will help with the transition. Gary Gordon, M.D., Chief Medical Officer of Ayala, will also resign his position but is expected to continue in an advisory role for a period of time. The board of directors of the combined company is expected to consist of seven members: two designated by Advaxis, four designated by Ayala, and Mr. Berlin.

Insiders' Interests in the Proposed Transaction

21. Ayala insiders are the primary beneficiaries of the Proposed Transaction, not the Company's public stockholders. The Board and the Company's executive officers are conflicted because they will have secured unique benefits for themselves from the Proposed Transaction not available to Plaintiff and the public stockholders of Ayala.

22. Notably, certain Company insiders have secured positions for themselves with the combined company. For example, under the terms of the Merger Agreement, two Ayala designees will serve as directors on the Board of the surviving corporation following consummation of the Proposed Transaction.

The Proxy Statement Contains Material Misstatements and Omissions

23. The defendants filed a materially incomplete and misleading Proxy Statement with the SEC and disseminated it to Ayala's stockholders. The Proxy Statement misrepresents or omits material information that is necessary for the Company's stockholders to make an informed decision whether to vote their shares in favor of the Proposed Transaction or seek appraisal.

24. Specifically, as set forth below, the Proxy Statement fails to provide Company stockholders with material information or provides them with materially misleading information concerning: (i) Ayala's financial projections; and (ii) the inputs and assumptions underlying the financial analyses performed by the Company's financial advisor Torreya. Accordingly, Ayala

stockholders are being asked to vote in favor of the Proposed Transaction or seek appraisal without all material information at their disposal.

Material Omissions Concerning Ayala's Financial Projections

25. The Proxy Statement omits material information regarding Ayala's financial projections.

26. Specifically, the Proxy Statement sets forth that:

Torreya performed a DCF analysis of Ayala for the purpose of calculating an enterprise equity value Ayala Common Stock on a stand-alone basis based on the estimated present value of the standalone, ***after-tax free cash flows that Ayala was forecasted to generate during fiscal years ending December 31, 2023 through 2033***. For purposes of this analysis, Torreya used risk adjusted projections of free cash flows for fiscal years ending December 31, 2023 through 2033 provided Ayala management (the "Ayala Projections"). Forecasted free cash flows were calculated by taking revenue, subtracting cost of goods sold and operating expenses, adding tax expense (adjusted for Ayala's Net Operating Losses ("NOL") generated to date of \$130 million), depreciation and adjusting for changes in net working capital. ***The Ayala Projections included estimates of revenues for each product in Ayala's pipeline, adjusted by the probability of success specified by management.***

Proxy Statement at 164, emphasis added. The Proxy Statement fails, however, to disclose the estimates of revenues for each product in Ayala's pipeline, adjusted by the probability of success specified by management.

27. Additionally, the Proxy Statement discloses Ayala's free cash flow over the projection period but fails to disclose Ayala's after-tax free cash flows that Ayala was forecasted to generate during fiscal years ending December 31, 2023 through 2033.

28. The omission of this information renders the statements in the "Summary of the Ayala Projections" section of the Proxy Statement false and/or materially misleading in contravention of the Exchange Act.

Material Omissions Concerning Torreya's Financial Analyses

29. The Proxy Statement describes Torrey's fairness opinion and the various valuation analyses performed in support of its opinion. However, the description of Torrey's fairness opinion and analyses fails to include key inputs and assumptions underlying these analyses. Without this information, as described below, Ayala stockholders are unable to fully understand these analyses and, thus, are unable to determine what weight, if any, to place on Torrey's fairness opinion in determining whether to vote in favor of the Proposed Transaction.

30. With respect to Torrey's *Discounted Cash Flow Analysis*, the Proxy Statement sets forth:

Torrey performed a DCF analysis of Ayala for the purpose of calculating an enterprise equity value Ayala Common Stock on a stand-alone basis based on the estimated present value of the standalone, after-tax free cash flows that Ayala was forecasted to generate during fiscal years ending December 31, 2023 through 2033. For purposes of this analysis, Torrey used risk adjusted projections of free cash flows for fiscal years ending December 31, 2023 through 2033 provided Ayala management (the "Ayala Projections"). Forecasted free cash flows were calculated by taking revenue, subtracting cost of goods sold and operating expenses, adding tax expense (adjusted for Ayala's Net Operating Losses ("NOL") generated to date of \$130 million), depreciation and adjusting for changes in net working capital. The Ayala Projections included estimates of revenues for each product in Ayala's pipeline, adjusted by the probability of success specified by management.

Id., emphasis added. The Proxy Statement, however, fails to disclose: (i) quantification of Ayala's after-tax free cash flows that Ayala was forecasted to generate during fiscal years ending December 31, 2023 through 2033, used in the analysis; and (ii) quantification of the inputs and assumptions underlying the discount rate of 12%.

31. The omission of this information renders the statements in the "Summary of Financial Analysis by Torrey" section of the Proxy Statement false and/or materially misleading in contravention of the Exchange Act.

32. The Individual Defendants were aware of their duty to disclose the above-referenced omitted information and acted negligently (if not deliberately) in failing to include this information in the Proxy Statement. Absent disclosure of the foregoing material information prior to the stockholder vote on the Proposed Transaction, Plaintiff and the other stockholders of Ayala will be unable to make a sufficiently informed voting or appraisal decision in connection with the Proposed Transaction and are thus threatened with irreparable harm warranting the injunctive relief sought herein.

CLAIMS FOR RELIEF

COUNT I

Claims Against All Defendants for Violations of Section 14(a) of the Exchange Act and Rule 14a-9 Promulgated Thereunder

33. Plaintiff repeats all previous allegations as if set forth in full.

34. During the relevant period, defendants disseminated the false and misleading Proxy Statement specified above, which failed to disclose material facts necessary to make the statements, considering the circumstances under which they were made, not misleading in violation of Section 14(a) of the Exchange Act and SEC Rule 14a-9 promulgated thereunder.

35. By virtue of their positions within the Company, the defendants were aware of this information and of their duty to disclose this information in the Proxy Statement. The Proxy Statement was prepared, reviewed, and/or disseminated by the defendants. It misrepresents and/or omits material facts, including material information about (i) Ayala's financial projections; and (ii) the inputs and assumptions underlying Torrey's financial analyses. The defendants were at least negligent in filing the Proxy Statement with these materially false and misleading statements.

36. The omissions and false and misleading statements in the Proxy Statement are material in that a reasonable stockholder would consider them important in deciding how to vote on the Proposed Transaction.

37. By reason of the foregoing, the defendants have violated Section 14(a) of the Exchange Act and SEC Rule 14a-9(a) promulgated thereunder.

38. Because of the false and misleading statements in the Proxy Statement, Plaintiff is threatened with irreparable harm, rendering money damages inadequate. Therefore, injunctive relief is appropriate to ensure defendants' misconduct is corrected.

COUNT II

Claims Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

39. Plaintiff repeats all previous allegations as if set forth in full.

40. The Individual Defendants acted as controlling persons of Ayala within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their positions as officers and/or directors of Ayala, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements contained in the Proxy Statement filed with the SEC, they had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading.

41. Each of the Individual Defendants was provided with or had unlimited access to copies of the Proxy Statement and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

42. Each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company, and, therefore, is presumed to have had the power to control or influence the transactions giving rise to the securities violations as alleged herein and exercised the same. The Proxy Statement at issue contains the unanimous recommendation of each of the Individual Defendants to approve the Proposed Transaction. They were, thus, directly involved in the making of the Proxy Statement.

43. In addition, as the Proxy Statement sets forth at length, and as described herein, the Individual Defendants were each involved in negotiating, reviewing, and approving the Proposed Transaction. The Proxy Statement purports to describe the various issues and information that they reviewed and considered—descriptions the Company directors had input into.

44. By virtue of the foregoing, the Individual Defendants have violated Section 20(a) of the Exchange Act.

45. As set forth above, the Individual Defendants had the ability to exercise control over and did control a person or persons who have each violated Section 14(a) and SEC Rule 14a-9, promulgated thereunder, by their acts and omissions as alleged herein. By virtue of their positions as controlling persons, these defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' conduct, Ayala stockholders will be irreparably harmed.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment and preliminary and permanent relief, including injunctive relief, in his favor on behalf of Ayala, and against defendants, as follows:

A. Preliminarily and permanently enjoining defendants and all persons acting in concert with them from proceeding with, consummating, or closing the Proposed Transaction and any vote on the Proposed Transaction, unless and until defendants disclose and disseminate the material information identified above to Ayala stockholders;

B. In the event defendants consummate the Proposed Transaction, rescinding it and setting it aside or awarding rescissory damages to Plaintiff;

C. Declaring that defendants violated Sections 14(a) and/or 20(a) of the Exchange Act, as well as SEC Rule 14a-9 promulgated thereunder;

D. Awarding Plaintiff the costs of this action, including reasonable allowance for Plaintiff's attorneys' and experts' fees; and

E. Granting such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: December 15, 2022

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